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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,303	04/14/2000	Brian Haab	S99-066	9147

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/550,303	HAAB ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,13-16,18,31 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,13-16,18,31 and 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *04/03* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *0703* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 14 April 2003 in which claim 31 was amended, claims 11-12, 19-30 and 32 were canceled and claims 38-39 were added. It is noted that on page 6 (first paragraph), of the response, Applicant states that Claim 10 is amended. This statement is considered an error because the claims submitted with the papers of 14 April 2003 and the FAX'd set of corrected claims does not contain an amended Claim 10. It is further noted that the corrected claims submitted by FAX does not contain new Claim 40. This omission is deemed an error because the amendment submitted 14 April 2003 states that new Claim 40 is added and presents a new Claim 40. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 6 November 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 10, 13-16, 18, 31, 33-40 are under prosecution.

Inventorship

2. In view of the papers filed 14 April 2003, the inventorship in this nonprovisional application has been changed by the deletion of Brian Haab.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

The previous rejection under 35 U.S.C. 102(e) over Brown et al is withdrawn in view of the change in inventorship.

Specification

3. Applicant's amendment to the first paragraph of the Specification is acknowledged. The amendment has been entered.

4. The amendment filed 14 April 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New claims 38-40 have been added with the language "a microarray consisting essentially of a planar solid support". However, the specification as originally filed does not teach or describe the newly recited "consisting essentially of a planar solid support".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "a microarray consisting essentially of a planar solid support" is recited in new Claim 38 from which Claims 39 and 40 depend. The specification teaches the solid support is a glass slide or derivatized glass (page 15, lines 14-16 and 25-30). However, the specification does not teach or describe the newly claimed "consisting essentially of a planar solid support" nor does the specification teach or describe the meaning of the phrases "consisting essentially of".

Therefore, the specification fails to define or provide any disclosure to support the new claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED.

APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10, 13-15, 18, 31, 33-35 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966).

Regarding Claim 10, Beattie teaches a microarray of discrete polypeptides on a planar solid support as recited in Claim 31 and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52). Additionally, they teach binding reagents include antibody-antigen and ligand-receptor binding (Column 7, lines 20-21) and are effective for carrying out immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding (Column 15) and Zubay defines antibodies as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Beattie is silent with regard to binding reagent being a polypeptide. However, the polypeptide recited in Claim 10 is deemed to be inherent in the binding reagents in Beattie because their antigen-antibody and ligand-receptor binding reagents encompasses polypeptides which are effective for carrying out

immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding all of which clearly suggests their microarray encompasses a microarray of polypeptides. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the suggested polypeptides of Beattie to their microarray to thereby obtain a microarray of polypeptides for the obvious benefit of providing means for characterizing and/or identifying a multiplicity of polypeptide-binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3). The teaching of Beattie differs from the instantly claimed invention only in the process of making the microarray. However, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, because Beattie clearly suggests their microarray comprises polypeptides, the claimed microarray of polypeptides is obvious in view of the teaching of Beattie, even thought the microarray of Beattie is made by a different process.

Regarding Claim 13, Beattie teaches the microarray wherein the binding reagents include antibody-antigen binding (Column 7, lines 20-21) and are effective for carrying out immunochemical analysis of protein mixtures and receptor-ligand binding (Column 15). The claim is given the broadest reasonable interpretation consistent with the claim language and specification wherein "immunological receptors" are not defined. Therefore, because the antibody-antigen binding and immunochemical analysis of Beattie encompasses immunological receptors, Beattie teaches the claimed immunological receptors.

Regarding Claim 14, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antibodies (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antibodies. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antibodies as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antibody-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identifying clinically important antibody-binding reagents.

Regarding Claim 15, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 18, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify

native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

Regarding Claim 31, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a planar solid support wherein the microarray comprises 1000 or more discrete regions/cm^2 (Fig. 1, Column 5, line 66-Column 6, line 6 and Claims 1 and 15) they teach binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Zubay defines antibodies as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Beattie is silent with regard to binding reagent being a polypeptide. However, the polypeptide recited in Claim 31 is deemed to be inherent in the binding reagents in Beattie because their antigen-antibody and ligand-receptor binding reagents encompasses polypeptides which are effective for carrying out immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding all of which clearly suggests their microarray encompasses a microarray of polypeptides. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the suggested polypeptides of Beattie to their microarray to thereby obtain a microarray of polypeptides for the obvious benefit of providing means for characterizing and/or identifying a multiplicity of polypeptide-binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3).

Regarding Claim 33, Beattie teaches the microarray wherein the binding reagents include antibody-antigen binding (Column 7, lines 20-21) and are effective for carrying out immunochemical analysis of protein mixtures and receptor-ligand binding (Column 15). The claim is given the broadest reasonable interpretation consistent with the claim language and specification wherein "immunological receptors" are not defined. Therefore, because the antibody-antigen binding and immunochemical analysis of Beattie encompasses immunological receptors, Beattie teaches the claimed immunological receptors.

Regarding Claim 34, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antibodies (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antibodies. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antibodies as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antibody-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identifying clinically important antibody-binding reagents.

Regarding Claim 35, Beattie teach the microarray wherein the binding reagents include antibody-antigen binding reagents which clearly suggests a microarray comprising antigens (Column 7, lines 20-21) but the do not specifically teach their microarray comprises antigens. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the antibody-antigen binding reagents taught by Beattie and to provide a microarray comprising antigens as suggested by Beattie to thereby provide means for characterizing and/or identifying a multiplicity of antigen-specific binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3) for the obvious benefit of characterizing and/or identify clinically important antigen-binding reagents.

Regarding Claim 37, Beattie teach the microarray is useful for characterizing and/or identifying binding reactions (Abstract, lines 1-3) which clearly suggests the binding reagents retain their native structure because characterizing binding reactions requires conditions which simulate native conditions e.g. three-dimensional structure because absent native conditions, the characterization and/or identification would not determine binding reactions. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polypeptide array of Beattie to provide polypeptides which retain their native three-dimensional structure to thereby provide means to characterize and/or identify

native biological reactions for the obvious benefit of studying and/or diagnosing biological interactions as they occur in nature. The burden is on applicant to show that the claimed native three-dimensional structure is either different or non-obvious over that of Beattie.

Regarding Claims 38-39, Beattie teaches a microarray consisting essentially of a planar solid support comprising 1000 or more discrete regions/cm^2 (Fig. 1, Column 5, line 66-Column 6, line 6 and Claims 1 and 15) comprising binding reagents deposited at defined positions on a planar solid support wherein the microarray they teach binding reagents include antibody-antigen binding (Column 7, lines 20-21) and Zubay defines antibodies as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). The preceding rejection is based on judicial precedent following In re Fitzgerald, 205 USPQ 594 because Beattie is silent with regard to binding reagent being a polypeptide. However, the polypeptide recited in Claim 31 is deemed to be inherent in the binding reagents in Beattie because their antigen-antibody and ligand-receptor binding reagents encompasses polypeptides which are effective for carrying out immunochemical analysis of protein mixtures, epitope mapping, assay of receptor-ligand binding all of which clearly suggests their microarray encompasses a microarray of polypeptides. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the suggested polypeptides of Beattie to their microarray to thereby obtain a microarray of polypeptides for the obvious benefit of providing means for characterizing and/or identifying a multiplicity of polypeptide-binding reactions simultaneously as suggested by Beattie (Abstract, lines 1-3).

Regarding Claim 40, Beattie teaches the microarray of Claim 38. The teaching of Beattie differs from the instantly claimed invention only in the process of making the microarray. However, the courts have stated patentability of a product does not depend upon the process of making the product.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

> the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP 2113).

Therefore, because Beattie clearly suggests their microarray comprises polypeptides, the claimed microarray of polypeptides is obvious in view of the teaching of Beattie, even thought the microarray of Beattie is made by a different process.

Response to Arguments

9. Applicant states that the instant invention is drawn to a microarray of selected polypeptides of at least 50 amino acids wherein the microarray is on a planar support. Applicant argues that in contrast to the instant invention, Beattie does not teach or suggest a planar substrate. The argument has been considered but is not found persuasive because, while the substrate of Beattie et al does have "wells", the presence of the wells does not alter the fact that the substrate is planar (see Fig. 1A and Column 9, lines 45-59). Furthermore, Beattie teaches that the substrate is "rigid support" (Column 6, line 44) and they claim their support as "having oppositely facing first and second major surfaces" (Claim 1) which clearly defines a planar support. Again, the fact that the planar support has through holes or wells, does not alter the fact that the support is planar. Therefore, Beattie et al teach the planar substrate as claimed.

Applicant's comments regarding the references submitted with the response are acknowledged. However, the references do not overcome the prior art cited above because the cited references teach the claimed invention.

10. Claim 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, filed 10 April 1996) as defined by Zubay, G. (Biochemistry,3rd ed.

Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) as applied to Claim 10 above and further in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claims 16 and 36, Beattie teaches a microarray comprising binding reagents deposited at defined positions on a planar solid support (Claims 1 and 15) and they teach the volume of the deposited binding reagent is between 0.002 and 2 nl (Column 14, lines 16-52) but they do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Beattie and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

Response to Arguments

11. Applicant states that the instant invention is drawn to a microarray of selected polypeptides of at least 50 amino acids wherein the microarray is on a planar support. Applicant argues that in contrast to the instant invention, Beattie nor Van Ness teach or suggest a planar substrate. The argument has been considered but is not found persuasive because, while the substrate of Beattie et al does have "wells", the substrate is planar as discussed above (see Fig. 1A and Column 9, lines 45-59). Therefore, Beattie et al teach the planar substrate as claimed.

12. Claims 10, 13-15, 18, 31, 33-35 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent No. 4,591,570, issued 27 May 1986) as defined by Zubay, G. (Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) in view of Beattie et al (U.S. Patent No. 5,843,767, filed 28 October 1993).

Regarding Claim 10, Chang discloses a microarray of polypeptides (i.e. antibodies) as claimed in Claim 31 wherein the microarray is produced by the method of loading an aqueous solution of a selected polypeptide in a reagent-dispensing device having an elongate capillary channel adapted to hold a quantity of the reagent solution and having a tip region at which the solution in the channel forms a meniscus, tapping the tip of the dispensing device against a surface of a planar solid support at a defined position with a in impulse effective to break the meniscus in the capillary channel and deposit a selected volume between 0.002 and 2 nl of solution on the surface and repeating the loading and tapping until a microarray is formed (Column 3, lines 39-55) wherein the microarray comprises 100 or more discrete regions of discrete regions of distinct polypeptides per cm^2 of solid support (Column 7, lines 1-67 and Fig. 2) and antibodies are defined by Zubay as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2). Chang teaches that a square centimeter contains at least 400 regions per cm^2 (Table 2, Column 7, lines 26-37) but does not specifically teach 1000 or more discrete regions per cm^2. However, the instantly claimed 1000 or more discrete regions per cm^2 was well known in the art at the time the claimed invention was made as taught by Beattie who teach that high density microarrays are important for simultaneously conducting a multiplicity of reactions on a substrate (Column 2, lines 1-20 and Column 5, line 66-Column 6, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the region density of Chang with the at least 1000 or more discrete regions per cm^2 taught by Beattie for the obvious benefits of simultaneously conducting at least 1000 reactions on a substrate as taught by Beattie (Column 2, lines 1-20).

Furthermore, the courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Therefore, the instantly claimed microarray comprising 1000 or more regions per cm^2 is not patentably distinct from the teachings of Chang and Beattie.

Regarding Claim 13, Chang discloses the microarray wherein the polypeptides are immunological receptors i.e. antibodies (Column 7, lines 1-67).

Regarding Claim 14, Chang discloses the microarray wherein the immunological receptors are antibodies (Column 7, lines 1-67).

Regarding Claim 15, Chang discloses the microarray wherein the polypeptides are antigens (Column 4, lines 61-66).

Regarding Claim 18, Chang discloses the microarray wherein the polypeptides retain the binding properties of the native polypeptide conferred by the three-dimensional structure i.e. the analyte-specific reagent is one member of ligand/anti-ligand pair wherein the analyte-specific reagent on the microarray binds to its binding partner for identification of the analyte. As such, the analyte-specific reagent maintains the binding properties of the native polypeptide to thereby identify the analyte for which it is specific (Column 7, line 40-Column 8, line 29).

Regarding Claim 31, Chang discloses a microarray of discrete polypeptides e.g. antibodies (Column 6, lines 20-28 and Column 15, lines 52-58) which are defined by Zubay as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2) wherein the microarray comprises 100 or more discrete regions of discrete regions of distinct polypeptides

per cm^2 of solid support (Column 3, lines 39-55). Chang teaches that a square centimeter contains at least 400 regions per cm^2 (Table 2, Column 7, lines 26-37) but does not specifically teach 1000 or more discrete regions per cm^2. However, the instantly claimed 1000 or more discrete regions per cm^2 was well known in the art at the time the claimed invention was made as taught by Beattie who teach that high density microarrays are important for simultaneously conducting a multiplicity of reactions on a substrate (Column 2, lines 1-20 and Column 5, line 66-Column 6, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the region density of Chang with the at least 1000 or more discrete regions per cm^2 taught by Beattie for the obvious benefits of simultaneously conducting at least 1000 reactions on a substrate as taught by Beattie (Column 2, lines 1-20).

Regarding Claim 33, Chang discloses the microarray wherein the polypeptides are immunological receptors i.e. antibodies (Column 7, lines 1-67).

Regarding Claim 34, Chang discloses the microarray wherein the immunological receptors are antibodies (Column 7, lines 1-67).

Regarding Claim 35, Chang discloses the microarray wherein the polypeptides are antigens (Column 4, lines 61-66).

Regarding Claim 37, Chang discloses the microarray wherein the polypeptides retain the binding properties of the native polypeptide conferred by the three-dimensional structure i.e. the analyte-specific reagent is one member of ligand/anti-ligand pair wherein the analyte-specific reagent on the microarray binds to its binding partner for identification of the analyte. As such, the analyte-specific reagent maintains the binding properties of the native polypeptide to thereby identify the analyte for which it is specific (Column 7, line 40-Column 8, line 29).

Regarding Claims 38-39, Chang discloses a microarray consisting of a planar solid support comprising 100 or more discrete regions of discrete regions of distinct polypeptides per cm^2 of solid support (Column 3, lines 39-55)of discrete polypeptides e.g. antibodies (Column 6, lines 20-28 and Column 15, lines 52-58) which are defined by Zubay as being

polypeptides of at least 50 amino acids in length (page 965, fig. 33.2) and Chang teaches that a square centimeter contains at least 400 regions per cm^2 (Table 2, Column 7, lines 26-37) but does not specifically teach 1000 or more discrete regions per cm^2. However, the instantly claimed 1000 or more discrete regions per cm^2 was well known in the art at the time the claimed invention was made as taught by Beattie who teach that high density microarrays are important for simultaneously conducting a multiplicity of reactions on a substrate (Column 2, lines 1-20 and Column 5, line 66-Column 6, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the region density of Chang with the at least 1000 or more discrete regions per cm^2 taught by Beattie for the obvious benefits of simultaneously conducting at least 1000 reactions on a substrate as taught by Beattie (Column 2, lines 1-20).

Regarding Claim 40, Chang teaches the microarray of Claim 38 wherein the microarray is produced by the method of loading an aqueous solution of a selected polypeptide in a reagent-dispensing device having an elongate capillary channel adapted to hold a quantity of the reagent solution and having a tip region at which the solution in the channel forms a meniscus, tapping the tip of the dispensing device against a surface of a planar solid support at a defined position with a in impulse effective to break the meniscus in the capillary channel and deposit a selected volume between 0.002 and 2 nl of solution on the surface and repeating the loading and tapping until a microarray is formed (Column 3, lines 39-55)

13. Claim 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent No. 4,591,570, issued 27 May 1986) as defined by Zubay, G.

(Biochemistry,3rd ed. Wm C. Brown Pub., Dubuque Iowa, 1993, pages 964-966) view of Beattie et al (U.S. Patent No. 5,843,767, filed 28 October 1993) as applied to Claim 10 above and further in view of Van Ness et al. (U.S. Patent No. 5,667,976, filed 14 February 1996).

Regarding Claims 16 and 36, Chang discloses a microarray of discrete polypeptides e.g. antibodies (Column 6, lines 20-28 and Column 15, lines 52-58) which are defined by Zubay as being polypeptides of at least 50 amino acids in length (page 965, fig. 33.2) wherein the microarray comprises 100 or more discrete regions of discrete regions of distinct polypeptides per cm^2 of solid support (Column 3, lines 39-55). And Beattie teaches a similar microarray comprising 1000 or more discrete sites (Column 5, line 66-Column 6, line 6). But Chang and Beattie do not teach a cationic film on the solid support capable of binding said polypeptide. However, cationic films on solid supports for binding polypeptides were well known in the art at the time the claimed invention was made as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide (Column 4, line 54-Column 5, line 7 and Column 6, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Chang and Beattie and to provide a cationic film on the solid support as taught by Van Ness et al. for the expected benefit of convenience of attachment as taught by Van Ness et al. (Column 6, lines 23-30).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 8, 2003